DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-719/S-105

Wyeth Pharmaceuticals, Inc.
Attention: Tracy D. Rockney
Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Rockney:

Please refer to your supplemental new drug application dated June 30, 2003, received July 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methotrexate Sodium for Injection, Methotrexate Sodium Injection.

This "Changes Being Effected" supplemental application provides changes to the label related to the divestiture of the Methotrexate Tablet NDA.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 30, 2003.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul Zimmerman, Project Manager, at (301) 594-5775.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Dotti Pease
7/29/03 03:11:02 PM